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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,283	09/30/2003	Stephen Allen Goldman	CM2653CL	5474

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EXAMINER	
WU, IVES J	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,283	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Ives Wu	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1). Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coles et al (US006613030B1).

Coles et al (US006613030B1) disclose hydrogel adhesive used with disposable absorbent articles, this adhesive provides secure attachment and are pleasing to the skin upon application, no discomfort upon removal; the rheological properties of elastic modulus and viscosity for this adhesives are disclosed. The composition of each major component (plasticizer – humectant, cross-linked hydrophilic polymer, water) are disclosed. The composition of cross-linked hydrophilic polymer is disclosed, preferably as three major types of acrylated-based monomer with their weight percentage range. The disposable articles, functional articles and protective articles with adhesives are disclosed.

As to the component of cross-linked hydrophilic polymer from 10 – 60 wt % in a hydrogel adhesive in **independent claim 1**, Coles et al disclose as cited: The adhesive is thus typically formed by polymerizing an aqueous reaction comprising from **5 to 50 wt %** of hydrophilic monomer, Col. 14, line 25-28; According to the patentee's invention the polymer component of the adhesive can be physically or chemically crosslinked in order to form 3 dimensional matrix, Col. 7, line 21-23.

As to the component of water-soluble non-ionic humectant from 5 to 80 wt % in a hydrogel adhesive in **independent claim 1**, Coles et al disclose as cited: The compositions according to the invention generally comprise, in addition to a crosslinked polymeric network, an aqueous plasticizers are generally used in the invention to control adhesive properties. The aqueous plasticizing medium optionally additionally comprises a polymeric or non-polymeric polyhydric

alcohol(such as glycerol), Col. 11, line 44-51; The aqueous reactive mixture preferably comprises from **10 to 50 %** of plasticizer (other than water) by weight of the mixture, Col. 11, line 55-57; Whilst the presence of glycerol or other polyhydric alcohols in other reported formulations has been quoted to provide **humectant properties to the hydrogel**, Col. 7, line 67 – Col. 8, line 3.

As to the component of water from 10 to 85 wt % in a hydrogel adhesive in **independent claim 1**, Coles et al disclose as cited: The adhesive is thus typically formed by polymerizing an aqueous reaction comprising **3 to 40 %** by weight of the reaction mixture, of **water,** Col. 14, line 25-34.

As to the component of weak acid monomer unit at least 50 mol% in the hydrophilic polymer in **independent claim 1**, Coles et al disclose as cited: In preferred embodiments the first and second monomers will be acrylate based monomers selected for their ability to polymerize rapidly in water, Col. 9, line 16-18; The first monomer is preferably included in an amount of from 1 to 60%, the second monomer is preferably included in an amount from 1 to 50 wt%, Col. 10, line 30-34; Additional monomer – A preferred anionic monomer is an acrylate based monomer such as acrylic acid or a salt or ester thereof, Col. 11, line 41-42; The weak acid monomer such as acrylic acid monomer is calculated to be the balance of amount used for first monomer and second monomer in the hydrophilic polymer, if the amount of first monomer used is small as 1 wt% and amount of second monomer used is small as 1 wt%, then the amount of weak acid (acrylic acid) will be at least 50-mol% of the hydrophilic polymer.

As to the component of weak acid monomer units comprising at least 50 mol % in their acidic form in **independent claim 1**, the disclosure of Coles et al meets this limitation by using same amount of acrylic acid and same amount of alkali metal salt of acrylic acid (3-sulphopropyl)ester or an analogue thereof for hydrophilic polymer, Col. 10, line 11-13, Col. 11, line 41-42;

As to acidic value of weak acid having a pKa above 3 in **independent claim 1**, the weak acid such as acrylic acid is 4.25 pKa (page 8-48, CRC Handbook of Chemistry and Physics, 85th ed).

As to the component salt form of all monomer units in hydrophilic polymer less than 30 mol % in **independent claim 1**, the invention of Coles et al meets the limitation by adjusting the amount of 2nd monomer which is salt so that the composition of hydrophilic polymer will contain less than 30 mol% salt form monomer units because the amount of 2nd monomer is adjustable from 1 to 50 wt% of the hydrophilic polymer mixture, Col. 10, line 32-34.

As to the elastic modulus at a temperature of 25 °C, G'_{25} (1 rad/sec),ranging from 2000 Pa to 6000 Pa in **independent claim 1**, Coles et al disclose: According to the invention there is provided a bioadhesive composition characterized in that it has: (ii) an elastic modules at 1 rad/s of from 700 Pa to 15,000 Pa, Col. 8, line 21-24; Typically the elastic modulus is measured over a range of 0.01-100 rad/s at a given temperature. For skin applications the appropriate temperature is 37 °C, Col. 8, line 34-37. Although the elastic modulus of Coles et al is measured at 37 °C, it would include the range of 2000 Pa –6000

Pa if Hydrogel adhesive of Cole et al with same composition of instant claim 1 is measure at 25°C. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

As to the limitation of **dependent claims 2 & 4,** The hydrogel of Coles et al meets the limitation by using small amount of 1st monomer such as 1 wt%, small amount of 2nd monomer such as 1 wt%, then the additional monomer – weak acid will be balanced to be more than 70 mol% and 80 mol% of the hydrophilic polymer.

As to limitation of **dependent 3**, Coles et al disclose as cited: A preferred anionic monomer is an acrylate based monomer such as **acrylic acid**, Col. 11, line 41-42.

As to limitation of **dependent 5 & 6**, Coles et al disclose as cited: Coles et al disclose as cited: The **aqueous** plasticizing medium optionally additionally comprises a polymeric or non-polymeric **polyhydric alcohol (**such as **glycerol),** Col. 11, line 49-51.

As to the limitation of **dependent claim 7**, in view of substantially identical hydrogel composition, it is examiner position to believe that the hydrogel of Coles et al will inherently possess the Saline Absorption Rate which is less than 2.5×10^{-3} g/cm^2/sec$^{0.5}$. Since USPTO does not have proper means to

conduct experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

As to the ratio of elastic modulus/viscous modulus to be in the range 0.15 to 0.65 in **dependent claim 8,** Coles et al disclose as cited: G_{37}' (1 rad/sec) is in the range 500 Pa – 20,000 Pa preferably 700 Pa to 15,000 Pa, most preferably 1000 Pa to 10,000 Pa. G_{37}" is in the range 100 Pa to 15,000 Pa, preferably 100 Pa to 10,000 Pa, most preferably 300 Pa to 5000 Pa. Therefore the ratio of G_{37}'= 500 Pa/G_{37}" =1000 Pa is 0.5 which is in the limitation of the claim 8.

As to the peel strength of hydrogel adhesive on dry skin ranging from 0.3 N/cm to 3.0 N/cm in **dependent claim 8,** Coles et al disclose the quantitative method to determining average peel force required to remove a skin at a specified peel angle and speed. However, Coles et al do not provide test results of samples. In view of substantially identical hydrogel composition, it is examiner position to believe that the hydrogel of Coles et al will inherently possess the Peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

As to the limitation of **dependent claim 9,** the disclosure of Coles et al meets the limitation by adjusting the amount of additional polymer -acrylic acid, and amount of the second monomer – alkali acrylic salt (it is adjustable between 1 – 50 wt% of total amount of monomer for hydrohilic polymer) and amount of 1st

monomer units (it is adjustable between 1 to 60 wt% of total amount units for hydrophilic polymer) so that the balance of weak acid – acrylic acid will be in 90 mol% and its acidic form units will be 85 mol%. For example, small amount such as 1 wt% of 1st monomer units is used, small amount of alkali acrylic salt such as 1 wt% of 2nd monomer units is used, then the large balance of weak acid – additional monomer unit will be 90 mol%, and the 2nd monomer units will be 5 mol%.

As to the limitation of **dependent claim 10,** Coles et al disclose as cited: According to the present invention the adhesive as described herein may also find application to attach other articles to the skin, Col. 18, line 36-38; The word "skin" according to the present invention (prior art) does not relate to the specific derma of the user but includes the mucous tissue as well as the hair which is typically found in the genital region, Col. 4, line 22-25.

As to the limitation of **dependent claim 11**, Coles et al disclose: The adhesive may also in addition find application to attach articles to the skin such as **ostomy devices**, Col. 18, line 67; Because the hydrogel adhesive disclosed by Coles et al is substantially identical to the hydrogel adhesive in the applicant's claim 1, it will be useful in a disposable human waste management by being disposed on a wearer facing surface as well, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937,939,136 USPQ 458,459 (CCPA 1963).

As to the limitation of **dependent claim 12,** Coles et al disclose as cited: The disposable absorbent article is described below by reference to a sanitary napkin, Col. 16, line 45-46; The sanitary napkin has two main surfaces, a body contacting or wearer facing surface on which the adhesive is applied and a garment facing or contacting surface, Col. 16, line 64-66.

As to the limitation of **dependent claim 13,** Coles et al disclose as cited: The adhesives may for example find utility to adhere functional articles which adhere to the skin such as cosmetic or pharmaceutical delivery articles which provide a substance to the skin such as skin treatment substances, cream, lotions, hormones, vitamins, deodorants, drugs; cosmetic or pharmaceutical delivery articles provide a substance to emanate away from the skin, Col. 18, line 38-44; The adhesive may also in addition find application to attach articles to the skin such as protective articles such as clothing, prosthesis, cold wraps thermal wraps, hearing aids, ornamental articles such as eye wear, goggles, Col. 18, line 52-67.

(2). As to the components of cross-linked hydrophilic polymer, humectant, water and their contents in the hydrogel adhesive composition in **independent claim 14,** the disclosure of Coles et al is incorporated herein as reference. These subject matters mentioned above in claim 14 have been recited in claim 1 and has been discussed in paragraph (1).

As to the composition of hydrophilic polymer comprising (1) at least 90 mol% of weak acid (2) these weak acid units being from 75 – 95 mol% in acidic form in **independent claim 14,** the disclosure of Coles et al meets the limitation by using small amount of 1st monomer such as less than 5 wt% of total mixture for hydrophilic polymer, large amount of additional monomer – weak acid (acrylic acid) so that its mol% will be at least 90 mol%, small amount of 2nd monomer unit of salt – alkali acrylic acid salt such as less than 5 wt% so that its mole content is less than 5%. Then, the result of weak acid monomer units in acidic form is in 75 - 95 mol% range for this combination.

As to the elastic modulus measured at 25 °C G'_{25}(1 rad/sec) ranging from 1,000 Pa to 10,000 Pa in **independent claim 14,** Coles et al disclose as cited: According to the invention there is provided a bioadhesive composition characterized in that it has: (ii) an elastic modules at 1 rad/s of from 700 Pa to 15,000 Pa, Col. 8, line 21-24; Typically the elastic modulus is measured over a range of 0.01-100 rad/s at a given temperature. For skin applications the appropriate temperature is 37 °C, Col. 8, line 34-37. Although the elastic modulus of Coles et al is measured at 37 °C, it would include the range of 1000 Pa – 10,000 Pa if hydrogel adhesive of Cole et al with same composition of instant claim 14 is measure at 25°C. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

As to hydrogel adhesive suitable for attachment to mammalian skin in **independent claim 14,** because the hydrogel adhesive disclosed by Coles et al is substantially identical to the hydrogel adhesive in the applicant's claim 14, it will be suitable for attachment to mammalian skin as well, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576,152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937,939,136 USPQ 458,459 (CCPA 1963).

As to the composition of hydrophilic polymer comprising at least 95 mol% weak acid monomer units, which has 85 to 95 mole % in acidic form in **dependent claim 15,** the same discussion for instant claim 14 by Coles et al is incorporated herein as reference. The composition of hydrophilic polymer is adjustable based on Coles et al disclosure so that the suitable amount of 1^{st} monomer units, 2^{nd} monomer units and additional monomer units will meet this limitation.

As to the elastic modulus G'_{25}(1 rad/sec) ranging from 4,000 Pa to 5,500 Pa in **dependent claim 15,** the same discussion for instant claim 14 by Coles et al is incorporated herein as reference. Although the elastic modulus of Coles et al is measured at 37 °C, it would include the range of 4000 Pa – 5,500 Pa if Hydrogel adhesive of Cole et al with same composition of instant claim 15 is measure at 25°C. Since USPTO does not have proper means to conduct

experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

As to the limitation of **dependent claim 16,** the disclosure of Coles et al is incorporated herein as reference. The most subject matters of humectant comprising glycerol and weak acid monomer units comprising acrylic acid in applicant's claim 16 has been recited in the applicant's claim 3 & 6 and has been discussed in paragraph (1).

As to the limitation of **dependent claim 17,** Coles et al disclose as cited: the 2nd monomer is a polymerisable sulphonate or a **salt**, e.g. an **alkali** metal salt such as sodium, potassium or lithium salt, of **acrylic acid** (3-sulphopropyl)ester or an analog thereof, Col. 10, line 10-13.

As to peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm and ratio G"25(1rad/sec)/G' 25(1rad/sec) ranging from 0.15 to 0.65 in **dependent claim 18,** in view of substantially identical hydrogel composition, it is examiner position to believe that the hydrogel of Coles et al with the same composition of applicant's claim 14 will inherently possess the Peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm and same ratio G"25(1rad/sec)/G' 25(1rad/sec) ranging from 0.15 to 0.65. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference; In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-1114. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner: Ives Wu
Art Unit: 1713

Date: July 15, 2005

DAVID W. WU
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